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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/069,703	04/29/98	TAPOLSKY	G VIRO:034

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EXAMINER

WEBMAN, E

ART UNIT	PAPER NUMBER
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1617

16

DATE MAILED:

01/08/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/669703

Applicant(s)

TAPOLSKY

Examiner

WGBMAN

Group Art Unit

1617

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 9/25/00
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-18, 33 is/are pending in the application.
- Of the above claim(s) 11, 14 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-10, 12, 13, 15-18, 33 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4, 11, 15
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

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A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 16 rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 3 of prior U.S. Patent No. 6,159,458. This is a double patenting rejection.

Claims 1-10, 12, 13, 15-18, 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 16 "CAPABLE" is vague; under what circumstances? In claims 15, 17 "anticholinergic" is misspelled, "antimenimic" is indefinite. In claim 10 "derivatives" is vague; which ones?

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1, 5, 6, 9, 11, 15, 17, 18, 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Kamiya et al.

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Kamiya et al teach a patch comprised of two water soluble layers (abstract). Antiseptics are specified (column 8 line 13). The examiner notes that Kamiya et al. Also reads on nonelected species in claims 3, 4, 11, 14 (see table I). Disclosed (column 4 lines 60-67).  
WATER IS

Claims 1-10, 12, 13, 15-18, 33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a flexible film comprising two water erodible layers and containing a drug, the first layer being an adhesive layer comprising a film forming polymer, does not reasonably provide enablement for a layered film, wherein the layer solubility is undefined (claim 17), not necessarily containing a drug (claim 1), and not necessarily claiming the recited polymers (claims 1, 17). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The scope of applicants independent claims is broader than the disclosure (see page 6 lines 6-28).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 6, 9, 11, 15, 17, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Inaba et al (U.S. patent 4,552,751 equivalent to EPA 0050480).

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Inaba et al teach a multilayered film comprising water soluble polymers (abstract). Prostaglandin E is specified (column 2 line 30). The examiner notes that Inaba et al discloses non elected species reading on claims 2-4, 11, 14 (see column 2 lines 1-28, examples 1, 3).

The disclosure is objected to because of the following informalities: On page 16 line 16 "antimenimic" is indefinite.

Appropriate correction is required.

No claims allowed.

Items lined through on PTO 1449 for the IDS filed 4/29/98, paper #4, are duplicates of those on PTO form 1449 for the IDS filed 9/25/00, paper # 15.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is (703) -308-4432. The examiner can normally be reached on Monday through Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Moezie, can be reached on (703) -308-0570. The fax phone number for the organization where this application or proceeding is assigned is (703) -305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) -308-1235.

Webman/LR

December 19, 2000

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EDWARD J. WEBMAN  
PRIMARY EXAMINER  
GROUP 1500